



**International  
Standard**

**ISO 19661**

**Traditional Chinese medicine —  
*Anemarrhena asphodeloides*  
rhizome**

*Médecine traditionnelle chinoise — Rhizome de Anemarrhena  
asphodeloides*

**First edition  
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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by ISO/TC 249, *Traditional medicine*, Subcommittee SC 1, *Traditional Chinese medicine*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

*Anemarrhena asphodeloides* rhizome (also known as Anemarrhena Rhizoma, Zhimu in Mandarin) is one of the commonly used herbal medicines in traditional Chinese medicine (TCM). For instance, of 1607 formulae in Chinese Pharmacopoeia (2020 edition), 44 contain the *Anemarrhena asphodeloides* rhizome (accounting for 2,74 %); among 148 kampo medicines for prescription from the Ministry of Health, Labour, and Welfare (MHLW) of Japan, 6 formulae contain the *Anemarrhena asphodeloides* rhizome (accounting for 4,05 %).

*Anemarrhena asphodeloides* rhizome was firstly recorded in “Shen Nong Ben Cao Jing”<sup>[1]</sup>, and has been used in TCM for a long time for treatment of external contraction of febrile disease, high fever with vexation and thirst, lung heat and dry cough, bone-steaming and tidal fever, interior heat wasting-thirst, constipation caused by intestinal dryness. Phytochemical investigations have revealed that *Anemarrhena asphodeloides* rhizome contains various chemical constituents, such as xanthenes, steroidal saponins, flavones, xylogen, tannins. Modern pharmacological studies have shown that the xanthenes and steroidal saponins are the main bioactive ingredients in *Anemarrhena asphodeloides* rhizome, which have the anti-diabetes, anti-inflammation, anti-tumour, anti-platelet aggregation and anti-thrombotic formation, cardioprotective, and cognition-enhancing effects.

In the global trade of *Anemarrhena asphodeloides* rhizome, China is the main export country. Based on the statistics report of the Department of Market Supervision, Ministry of Commerce of the People's Republic of China, from 2016 to 2020, the average annual export volume of *Anemarrhena asphodeloides* rhizome was 758 326,4 kilograms, worth USD 4 068 006. The main destination countries and regions included Japan, Hong Kong, the Republic of Korea, Taiwan (Province of China), Malaysia, Viet Nam, New Zealand, Germany, the United States and Thailand.

*Anemarrhena asphodeloides* rhizome has been recorded in the Pharmacopoeia of the People's Republic of China<sup>[2]</sup>, the European Pharmacopoeia<sup>[3]</sup>, the Japanese Pharmacopoeia<sup>[4]</sup> and the Korean Pharmacopoeia<sup>[5]</sup>, and the requirements of each pharmacopoeia are different. The standard of *Anemarrhena asphodeloides* rhizome has not been unified at the international level. Therefore, the establishment of an International Standard is necessary to guarantee the quality, safety, and consistency of the valuable herbal medicine.

As national and regional implementation can differ, national standards bodies are invited to modify the values given in 5.6 and 5.7 in their national and regional standards. Examples of national and regional values are given in Annex C.



# Traditional Chinese medicine — *Anemarrhena asphodeloides* rhizome

## 1 Scope

This document specifies the quality and safety requirements for *Anemarrhena asphodeloides* rhizome.

This document applies to *Anemarrhena asphodeloides* rhizome that is sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from the plant.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

ISO/TS 21310, *Traditional Chinese medicine — Microscopic examination of medicinal herbs*

ISO 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

ISO 22217, *Traditional Chinese medicine — Storage requirements for raw materials and decoction pieces*

ISO 22258, *Traditional Chinese medicine — Determination of pesticide residues in natural products by gas chromatography*

ISO 23723, *Traditional Chinese medicine — General requirements for herbal raw material and materia medica*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

### 3.1

#### ***Anemarrhena asphodeloides* rhizome**

dried rhizome of *Anemarrhena asphodeloides* Bunge

## 4 Description

*Anemarrhena asphodeloides* rhizome is collected in spring or autumn, with fibrous roots removed and dried under the sun, or with the outer cork removed and dried under the sun, as shown in [Figure 1](#).